World Health Organization

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In reply please refer to: GP/vl

Your reference: P17-370-9

Premier Medical Corporation Limited
For the attention of Dr Rajeshkumar Patel
Director and Technology Head
A1-302/ GIDC
Sarigam, Dist., Valsad
396 155
Inde

4 December 2018

Dear Dr Patel,

Subject: **WHO Prequalification of In Vitro Diagnostics – Final Public Report**
Product name: First Response®Malaria Ag. P.f. / P.v. Card Test
Product codes: PI19FRC10s, PI19FRC25s, PI19FRC30, and PI19FRC25
Regulatory version: rest-of-world
Manufacturer: Premier Medical Corporation Limited
PQDx Reference Number: 0329-010-00

We are pleased to inform you that the above-referenced product was prequalified on 4 December 2018 and listed on the World Health Organization (WHO) list of prequalified in vitro diagnostic products.

The following post-prequalification activities are required to maintain the prequalification status:

1. Notification to WHO of any planned changes to a prequalified product, in accordance with "*WHO procedure for changes to a WHO prequalified in vitro diagnostic*" (document number PQDx_121); and
2. Post-market surveillance activities, in accordance with "*WHO guidance on post-market surveillance of in vitro diagnostics*" (ISBN 978 92 4 150921 3).

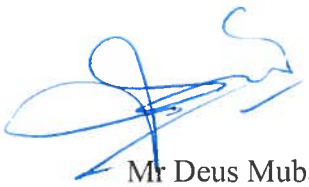
You are also required to submit an annual report that details sales data and all categories of complaints in a summarized form. There are certain categories of complaints and changes to the product that must be notified immediately to WHO, as per the above-mentioned documents. The sales data will serve as denominator data to guide the frequency of re-inspection.

ENCL: as stated

Failure to comply with any of the above-mentioned post-prequalification requirements may lead to remedial action by WHO, including but not limited to, de-listing from the WHO list of prequalified in vitro diagnostic products.

If you have any questions, please do not hesitate to contact us by email (diagnostics@who.int) or by telephone (+4122 791 2801).

Yours sincerely,



Mr Deus Mubangizi
Coordinator
Prequalification Team
Regulation of Medicines and other Health Technologies